

# HITACHI

FEB 17 2006

K053148

**HITACHI MEDICAL SYSTEMS AMERICA, INC.**  
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Twinsburg, Ohio 44087-2371  
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## 510(k) Summary

### Submitter Information

Submitter: Hitachi Medical Systems America, Inc.  
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Twinsburg, Ohio 44080-2371  
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Contact: Douglas J. Thistlethwaite  
Date: September, 15-2005

### Device Name

Device Name: Computed tomography x-ray system  
Trade/Proprietary Name: CXR16  
Common Name: Computed Tomography X-ray System  
Classification Name: System, X-Ray, Tomography, Computed  
Classification Number: Sec. 892.1750

### Predicate Device

Predicate Device: Hitachi Presto CT, 510(k) K040902

# Device Description

## Function

The CXR16 is a multi-slice computed tomography system that uses x-ray data to produce cross-sectional images of the body at various angles.

## Scientific Concepts

The CXR16 system uses “third generation” CT technology, where the x-ray tube and detector assemblies are mounted on a frame that rotates continuously around the patient using slip ring technology. The solid-state detector assembly design collects up to 16 slices of data simultaneously. The x-ray sub-system features a high frequency generator, x-ray tube, and collimation system that produces a fan beam x-ray output. The system can operate in a helical (spiral) scan mode where the patient table moves during scanning. As the x-ray tube/detector assembly rotates around the patient, data is collected at multiple angles.

The collected data is then reconstructed into cross-sectional images by a high-speed reconstruction sub-system. The images are displayed on a computer workstation, stored, printed, and archived as required. The workstation is based on current PC technology using the Windows™ operating system.

## Physical and Performance Characteristics

The CXR16 system consisting of a gantry, operator’s workstation, patient table, high-frequency x-ray generator, and accessories. The system performance is similar to the predicate device.

## Performance Comparison

Because the CXR16 and the predicate device are both Hitachi designs, they were subjected to the same non-clinical evaluations as stipulated in 21 CFR 1020.33(c). Evaluations include: dose profile, image noise, modulation transfer function (MTF), slice thickness and sensitivity profile, slice plane location, and CT dose index.

The evaluation results of the CXR16 were comparable to the predicate device and support our conclusion that the CXR16 CT system is substantially equivalent.

## Device Intended Use

The CXR16 Computed Tomography system is an x-ray imaging device that produces cross-sectional images of the body at different angles. The system reconstructs, processes, displays, and stores the collected images. The device output can provide an aid to diagnosis when used by a qualified physician.

## Device Technological Characteristics

The CXR16 CT system acquires data in the same manner as the predicate device. Physically, the CXR16 is very similar to the predicate device. The key differences are the ability to collect 16 slices in a single scan as well as improvements in overall technology.

The ability to collect 16 slices in a single scan allows overall scan time to be decreased but does not change the essential characteristics of the finished images. The predicate is a 4-slice design, meaning that if an area of 16 mm is to be examined in 2 mm increments, the x-ray tube must scan the patient 2 times, collecting 8 mm (4x2) of data for each scan, to produce 8 total images. In the CXR16 system's 16-slice design, the system need only to scan 1 times, collecting 16 mm of data during each scan. The x-ray beam is collimated to allow the exposure of 16 slices simultaneously, and the data collection system collects all 16 slices. Since the data collection system processes the data in 2 mm increments, the system produces 8 images as before, but during a shorter time.

The operation of the system is virtually identical to the predicate because both systems were produced using the same essential design concepts. The CXR16 operating system software is essentially the same, as well as the user interface. The patient table and gantry designs were updated. See the predicate comparison for detailed information.

Despite these differences, the CXR16 CT system is technologically equivalent in concept, function, and performance to the predicate device.

## Conclusions

The CXR16 CT system has been developed and validated according to applicable standards. Testing has proven that the system is safe and effective for the indicated use. Risk and hazard analysis shows that there are no new safety issues associated with this system as compared with the predicate device.



DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration  
9200 Corporate Boulevard  
Rockville MD 20850

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Hitachi Medical Systems America, Inc.  
% Mr. Neil E. Devine, Jr.  
Responsible Third Party Official  
Intertek Testing Services NA, Inc.  
70 Codman Hill Road  
BOXBOROUGH MA 01719

Re: K053148  
Trade/Device Name: CXR 16 Computed Tomography  
X-ray System  
Regulation Number: 21 CFR 892.1750  
Regulation Name: Computed tomography  
x-ray system  
Regulatory Class: II  
Product Code: JAK  
Dated: February 1, 2006  
Received: February 3, 2006

Dear Mr. Devine:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration.

If your device is classified (see above) into either class II (Special Controls) or class III (Premarket Approval), it may be subject to such additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

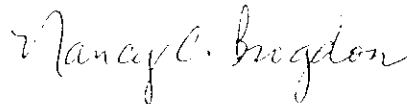
This letter will allow you to begin marketing your device as described in your Section 510(k) premarket notification. The FDA finding of substantial equivalence of your device to a legally marketed predicate device results in a classification for your device and thus, permits your device to proceed to the market.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please contact the Office of Compliance at one of the following numbers, based on the regulation number at the top of this letter:

21 CFR 876.xxxx	(Gastroenterology/Renal/Urology)	240-276-0115
21 CFR 884.xxxx	(Obstetrics/Gynecology)	240-276-0115
21 CFR 892.xxxx	(Radiology)	240-276-0120
Other		240-276-0100

Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21 CFR 807.97). You may obtain other general information on your responsibilities under the Act from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (301) 443-6597 or at its Internet address <http://www.fda.gov/cdrh/industry/support/index.html>.

Sincerely yours,



Nancy C. Brogdon  
Director, Division of Reproductive,  
Abdominal, and Radiological Devices  
Office of Device Evaluation  
Center for Devices and Radiological Health

Enclosure

## Indications for Use

510(k) Number (if known): K053148

Device Name: CXR16 Computed Tomography X-ray System

### Indications for Use:

The CXR16 Computed Tomography system is an x-ray imaging device that produces cross-sectional images of the body at different angles. The system reconstructs, processes, displays, and stores the collected images. The device output can provide an aid to diagnosis when used by a qualified physician.

Prescription Use X  
(Part 21 CFR 801 Subpart D)

AND/OR

Over-the-Counter Use \_\_\_\_\_  
(21 CFR 801 Subpart C)

(PLEASE DO NOT WRITE BELOW THIS LINE – CONTINUE ON ANOTHER PAGE IF NEEDED)

Concurrence of CDRH, Office of Device Evaluation (ODE)

David A. Lopez  
(Division Sign-Off)  
Division of Reproductive, Abdominal,  
and Radiological Devices  
510(k) Number K053148